



Food and Drug Administration  
10903 New Hampshire Avenue  
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April 22, 2016

Heraeus Medical GmbH  
% Mr. Gordon MacFarlane  
Senior Manager Regulatory Affairs  
ICON plc  
62 Forest Street  
Marlborough, Massachusetts 01752

Re: K153737

Trade/Device Name: OSTEOPAL® plus  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) bone cement  
Regulatory Class: Class II  
Product Code: LOD, NDN  
Dated: March 15, 2016  
Received: March 24, 2016

Dear Mr. MacFarlane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

510(k) Number (if known)  
K153737

Device Name  
OSTEOPAL® plus

Indications for Use (Describe)

OSTEOPAL® plus bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)       Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**Special 510(k)**

**510(k) Summary**

Date of summary	March 15 <sup>th</sup> , 2016
Applicant's name and address	Heraeus Medical GmbH Philipp-Reis-Straße 8/13 61273 Wehrheim Germany
Device trade name	OSTEOPAL® plus
Common name	PMMA Bone Cement
Classification	PMMA Bone Cement : Class II special control per 21 CFR 888.3027
Classification name	Polymethylmethacrylate (PMMA) bone cement
Product code	LOD, NDN
Identification of the marketed device to which equivalence is claimed	OSTEOPAL® V, K050085
Description of the device	OSTEOPAL® plus is a radiopaque, low-viscosity bone cement, based on polymethyl methacrylate with an extended application phase, used to fill and stabilize vertebral bodies. OSTEOPAL® plus contains zirconium dioxide as an X-ray contrast agent. OSTEOPAL® plus contains the coloring agent chlorophyll VIII (E141) to improve visibility in the surgical field. The bone cement is prepared immediately prior to use by mixing the polymer powder component and the liquid monomer component. A low viscosity paste is applied with the use of application system, placed in the vertebral body, where it cures. OSTEOPAL® plus conforms to ISO 5833 except Annex C

**Special 510(k)**

**510(k) Summary**

Intended use	OSTEOPAL® plus bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.
Comparison of technological characteristics	Bone cement is derived by mixing a powder component and a monomer liquid. The only difference between the subject and predicate device is a change to the monomer liquid composition and therefore an extended setting time.
Discussion of nonclinical tests	<p>The maximum temperature, setting time, compressive strength, bending modulus and bending strength of OSTEOPAL® plus was characterized per ISO 5833. Both the subject and predicate device disclose a higher curing time, with OSTEOPAL® plus displaying an even increased setting time. These prolonged working phases are needed because for augmentation of vertebral bodies longer setting times than described in ISO 5833 are necessary. Therefore, the later setting time is advantageous. In addition, impact and bending strength were measured according to Dynstat test method. EtO sterilization was validated per ISO 11135. Biocompatibility testing, including cytotoxicity, irritation, sensitization, acute systemic toxicity was performed per ISO 10993.</p> <p>As PALACOS® R, K030902 (the predicate device for polymerized OSTEOPAL® V) is made of the same material constituents as OSTEOPAL® plus and the performed tests regarding genotoxicity are very sensitive it is reasonable that the results are</p>

**Special 510(k)**

**510(k) Summary**

	transferable. Thus it can be concluded that OSTEOPAL® plus is not genotoxic.
Clinical performance data	No clinical data was provided.
Conclusions from nonclinical and clinical data	OSTEOPAL® plus is substantial equivalent to OSTEOPAL® V.
Submitted by	Dr. Astrid Marx Phone: + 49 (0) 6181.35-2963 Fax: + 49 (0) 6181.35-2916 <a href="mailto:astrid.marx@heraeus.com">astrid.marx@heraeus.com</a>
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